

510(K) SUMMARY

This 510(k) Summary is provided in accordance with 21 CFR 807.92.

Date of preparation: 14 November 2011

Submitter information:

Calypso Medical Technologies, Inc.
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Contact: Marcia A Page
Vice President Quality Assurance and Regulatory Affairs

Device trade name: Calypso® System with Dynamic Edge™ Gating

Common name: Patient localization system

Classification name: Medical charged-particle radiation therapy system

Classification: CFR 892.5050
Class II
Product code – LHN, IYE

Predicate devices: Calypso® 4D Localization System (K060906, K080726, K102373)

Device Description:

The Calypso System utilizes non-ionizing electromagnetic and optical technology to provide accurate, objective, and continuous localization of a treatment target for patient alignment and target position monitoring during radiation therapy. Use of the Calypso System for target localization is based on the system's detection of non-ionizing electromagnetic signals from passive markers, called Beacon® transponders. The Beacon Transponders are implanted in either the prostate or the peri-prostatic tissue (i.e., prostatic bed). When used with the Calypso System, the Beacon transponder signals enable objective measurement of the location of the treatment target in 3 dimensions.

The system operator uses this information to align the patient's treatment target to the isocenter of the therapy system prior to treatment. This information can also be used to monitor (track) the position of the treatment target during radiation therapy treatment.

The Dynamic Edge Gating feature enables the Calypso System to connect with radiation therapy systems configured with gating capabilities via an interface to external systems. With this feature added to the Calypso System, a beam hold is signaled to the radiation therapy system when the treatment target position has moved outside the defined tracking limits. The radiation therapy system is signaled to remove the beam-hold upon the target's return to a position inside the defined tracking limits.

Indications for Use:

The Calypso® System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon® transponders.

The optional Dynamic Edge™ Gating component may signal a radiation therapy system to impose a beam-hold when the treatment target position has moved outside the defined tracking limits and to signal the radiation therapy system to remove the beam-hold upon the target's return to a position inside the defined tracking limits. The Dynamic Edge Gating feature has been shown to be compatible with Varian and Siemens radiation therapy treatment systems with external gating interfaces.

Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures.

Permanent Beacon transponders are indicated for permanent implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed).

Technological Characteristics – See device comparison table below

Feature and/or Specification of new/modified device	K102373 Cleared Device Feature/Specification	Device with Change
Infrared optical system	Cameras and infrared targets on array and Beacon Transponders	No change
Monitoring	Real Time Monitor patient motion	No change
Tracking	Real Time Tracking Patient motion	No change
Gating	Interface to external systems	No change
Records	Display and Record motion	No change
Computer hardware and software	Computer systems (console and tracking station) to control device functions and provide for user interface	No change
Electromagnetic technology (array)	Used to track motion during therapeutic procedures	No change
compatibility with the environment and other devices	Operates in a radiation therapy system environment	No change
electrical safety mechanical safety	IEC 60601-1; IEC 60601-1-1	No change
EMC Safety	IEC 60601-1-2	No change

Summary of Performance Testing:

There has been no change to the device performance, software or hardware. Testing performed in support of K102373 demonstrated substantial equivalency and safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Marcia Page
Vice President Quality Assurance and Regulatory Affairs
Calypso Medical Technologies, Inc.
2101 4th Avenue, Suite 500
SEATTLE WA 98121

NOV 18 2011

Re: K112768
Trade/Device Name: Calypso® System with Dynamic Edge™ Gating
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN and IYE
Dated: September 21, 2011
Received: September 22, 2011

Dear Ms. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, reading "Mary S. Pastel". The signature is fluid and cursive, with the first name "Mary" being more prominent than the last name "Pastel".

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE510(k) Number (if known): K112768Device Name: Calypso® System with Dynamic Edge™ Gating**Indications for Use:**

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Prescription Use X
(Part 21 CFR 801 Subpart D)AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K112768